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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,878	09/26/2003	Jennie P. Mather	415072000101	9515

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,878	MATHER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,15 and 18-37* is/are pending in the application.

4a) Of the above claim(s) *7,18-27,34,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,15,28-33,35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/06 has been entered.

2. Newly submitted claims 34, 36 and 37 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants have elected RL-65 cells in the response to the restriction filed 2/25/05. However, the species recited in claims 34, 36 and 37 includes various cells and they are not supported by the originally elected species, RL-65. These species are distinct because of their structural or physicochemical properties and modes of action. Therefore, they are patentably distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34, 36 and 37 are withdrawn from consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, claims 1-6, 8, 9, 15, 28-33 and 35are under consideration in the instant application.

3. Upon Applicants' amendment and cancellation to claims, the following rejection remains.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-6, 8, 9, 15, 28-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okabe et al. (Cancer Res., 1984, 44:5273-5278, IDS reference 37, of record) in view of U. S. Pat. No. 5,364,785 (IDS reference 1), of record as is evidenced by the U.S. Pat. No. 5,932,704 (IDS reference, newly cited).

Okabe et al. teach a method for producing monoclonal antibodies that bind to antigens that are heterologous to a host mammal such as human small cell carcinoma cells of the lung to a BALB/c mice, (abstract, and material and methods, p. 5273, in particular), immunizing the host, fusing lymphoid cells, culturing hybridoma and selecting the hybridoma by immunoassay (p. 5273, col. 2, radioimmunoassay, in particular), cell sorting process (FACS) (abstract, p. 5274, col. 1, 1st paragraph, in particular) and functional effect (complement-mediated cell lysis) of antibody (p.5274 col.1, 2nd paragraph, in particular).

Okabe et al. further teach the antigen is on the surface membrane (abstract, in particular), the origin of the cells are embryonic, and endodermic (p. 5278, discussion, in particular) and the antibodies specific for the surface antigens are potentially important for diagnostic and therapeutic tools (introduction, in particular).

The claimed invention differs from the reference teachings by using the intact cells (RL-65) grown in the serum free media, morphology of cells and biological substrate.

However, the '785 patent teaches the isolation of a single epithelial cell type from lung tissue (col. 2, lines 64-68, in particular), a method of isolating an epithelial lung cell line (RL-65) in the serum free media (col. 2-3 overlapping paragraph, in particular), immortalized (i.e. grow over 2 yrs in continuous culture col. 2, lines 20-22, in particular) and the cell line is suitable for homologous protein production,

heterologous protein expression (i.e. cell specific antigen, col. 4, lines 61-69 and col. 5, lines 1-6, in particular).

The '785 patent further teaches a cell growth in the form of monolayer (col. 7, lines 33-36, in particular), aggregates (i.e. colony, col. 7, lines 33-36, in particular), and on a fibronectin substrate (col. 7, lines 30-32, in particular).

In addition, the '785 patent further teaches the functions of lungs have been difficult to study *in vitro* because of diverse cell types (col. 1, lines 25-31, col. 2, lines 61-69) and the non-tranformed epithelial cell lines from the normal tissue would be of great use in furthering understanding of lung endocrinology and physiology (col. 2, lines 1-9, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ an isolated epithelial cell line RL-65 taught by the '785 patent in a method of monoclonal antibody generation taught by Okabe et al.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because the generation of epithelial cell specific monoclonal antibodies would be provided to study lung endocrinology and physiology as taught by the '785 patent.

From the combined teachings of references, one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence to the contrary.

Applicants' arguments filed on 10/30/06 have been fully considered but they are not persuasive.

Applicants argue that Okabe does not teach all the limitations of the claimed invention, (i.e. without adjuvant, or intact cells). Applicants further traversed the rejection based on that Okabe et al. does not disclose whether or not adjuvant was used for immunizing cells. In the declaration under the 37.C.F.R. 1.132 filed on 9/26/05, which was previously considered, applicants state it is a general practice to use an adjuvant in immunization.

Even though the lack of experimental details is not the confirmation that the adjuvant was used in Okabe et al., contrary to Applicants' argument, it is well known to immunize mammals with the viable cells to produce antibodies without adjuvant. As is evidenced by the '704 patent, col. 4, lines 5-27, the immunization of mice or mammals without adjuvant to produce antibodies was well known in the art.

In addition, the claim 1 as amended, does not require "without adjuvant" when is introduced into the mammal. The phrase "and the...without adjuvant" in claim 1, lines 5-6 has been removed and the method now reads on "with adjuvant".

Moreover, Applicants argue that the Okabe reference does not teach viable cells because the tumor was minced. However, the tumors were minced to generate "TNSC-1" or "TNSC-2" cells and those cells are intact (p. 5273 and abstract, in particular). Thus, the limitation has been taught and the combination of teaching remains obvious.

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Yunsoo Kim
Patent Examiner
Technology Center 1600
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